510(k): k112752

MAY 10 2012

EXHIBIT 2

510(K) Summary

1.	**Submitter Name:**	Oryx Medical Pty Ltd
2.	**Address:**	4/43 Caledonian Avenue, Maylands WA Australia 6051
3.	**Phone:**	+61 8 6142 2311
4.	**Fax:**	+61 8 6142 2311
5.	**Email:**	tony@oryxmedical.com
6.	**Contact:**	Tony Horstman
7.	**Establishment Registration Number:**	Not yet received
8.	**Date summary prepared:**	17 March 2010
9.	**Device Trade or Proprietary Name:**	ilwait timer oculopressor
10.	**Device Common Name or Usual Name:**	Ocular Pressure Applicator
11.	**Device Classification Name:**	Applicator, ocular pressure
12.	**Device Classification Code:**	LCC
13.	**Device Class:**	2 as per 886.4610 Ocular pressure applicator
14.	**Compliance (performance standards):**	None established under Section 513-514
15.	**Predicate Device(s):**	Honan Intraocular Pressure Reducer

16. **Device Description:**

The ***ilwait timer oculopressor*** is an orbital ocular compression applicator comprising a mass which applies a suitable force under gravity against the closed eyelid of a supine patient for the purpose of performing pre-operative ocular compression.

The static pressure applied by the device assists in the diffusion of anaesthetic agents that may accumulate or be resident under the conjunctival membrane (chemosis) and surrounding tissues following retrobulbar, peribulbar and subtenons anaesthetic administration, and softens the eye by forcing intraocular fluid from the globe via the natural pressure regulation pathways.

Clinical function of the device is dependant only on positioning to the patient and does not indicate patient condition, and presents very little information, thus the device itself does not present significant judgement risks or risk of cognitive / recall error.

The ***ilwait timer oculopressor*** has no control or interaction with other devices or drugs, however use of the device on the eye may assist the action of the dispersal or anaesthetic agents applied. The action is not co-dependent.

Clinically the eye recovers naturally from compression within a short period and there are no cumulative effects known from safe, monitored compression at this level.

The ***ilwait timer oculopressor*** is located to the patient's head with an adjustable strap fitted to provide access to the left or right eye socket. The fixation of the device to this strap allows a static, balanced device position to be maintained. Patients are commonly sedated and remain in a comfortable position to reduce movement which may alter the device position. Patients are always monitored during pre-surgical preparation. The device is applied, monitored and adjusted as necessary throughout application by trained staff ranging from theatre nurses, pre-operative ward staff or the anaesthetist.

Medical staff including highly trained operating theatre nurses or the anaesthetists or the practitioner position and control the device. The patient head position may influence device the stability and the medical staff can adjustment the device for suitable position. The patient is kept quiet as movement may dislodge the device or force repositioning of the device.

The use of the compression function of the device is presented in a known and easily recognisable format, with ergonomic factors, such as the concave cushion and recessed grip areas providing visual clues to operation and positioning.

The device has positive handling and grip areas to assist the medical staff. The mass is formed with recessed areas to assist grip and the strap components provide grasping areas. The contact surface formation is smooth and generally conforms to eyelid shape.

The ***ilwait timer oculopressor*** incorporates a user-activated cumulative stopwatch timer to record total duration of application, with an upper limit (including programmed pauses) indicated by a visual and audible interface warning at 23 minutes.

17. Indications for Use:

The ***ilwait timer oculopressor*** device is used to perform pre-operative ocular compression.

The device is used in the clinical and pre-operative ward, when the patient is supine, sedated and accompanied by a medical staff member.

The mass of the ***ilwait timer oculopressor*** provides even pressure across the eyelid to soften the eye.

The timer function provides a reminder to monitor the compression duration

18. Summary Comparing Technological Characteristics with Predicate Devices:

Oryx Medical makes a Substantial Equivalence claim for the ilwait timer oculopressor to the Honan Intraocular Pressure Reducer, 510(k) # K820526. Both devices are used for the same application of reducing ocular pressure prior to ophthalmic surgery. Both devices are similar and in some cases use the same type of accessories such as headstrap.

Both devices apply pressure to the closed eye prior to surgery, although the ilwait timer oculopressor applies a static pressure derived from a mass under gravity compared to the Honan Intraocular Pressure reducer by which variable air pressure is applied dependent on the medical staff. Both are supplied non-sterile and reusable. Honan is also supplied as disposable device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Oryx Medical Pty, Ltd.
c/o Ms. Anne Francis Jones
Regulatory & Quality Consultant
Acrapack Pty, Ltd.
34 Myles Street
Tweantin, QLD 4565
Australia

MAY 10 2012

Re: K112952
Trade/Device Name: i|wait timer oculopressor
Regulation Number: 21 CFR 886.4610
Regulation Name: Ocular pressure applicator
Regulatory Class: II
Product Code: LCC
Dated: March 22, 2012
Received: April 6, 2012

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jessica Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT 1 j

INDICATIONS FOR USE

Indications for Use

510(k) Number (if known):

Device Name: ilwait timer oculopressor

Indications for Use

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The timer function provides a reminder to monitor the compression duration.

Prescription Use: X AND / OR Over- the-Counter Use: ____

(Part 21 CFR Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K112952